



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/591,100

10/25/2006

Immanuel Straub

516/12

6349

27538 7590 12/10/2008
GIBSON & DERNIER L.L.P.
900 ROUTE 9 NORTH
SUITE 504
WOODBIDGE, NJ 07095

EXAMINER

EASTWOOD, DAVID C

ART UNIT

PAPER NUMBER

4185

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,100	Applicant(s) STRAUB, IMMANUEL	
	Examiner DAVID EASTWOOD	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/30/2006,9/25/2006,10/25/2006,9/28/2007.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1-2, 5-13, 18, and 23-24 rejected under 35 U.S.C. 102(b) as being anticipated by Straub et al (US 5873882).

Regarding Claim 1, Straub et al discloses *a working head that is axially displaceable over a guide wire, is displaceable independently of the guide wire, is arranged at a distal end of the catheter and has at least one lateral opening.* (Column 3 Lines 65-67 and Column 4 lines 1-8), (Figure 2 and 3 item 16) *a flexible transport screw that has a distal and a proximal part and is capable of being rotated by means of*

a rotary drive of a drive unit the rotary drive being a distance away from the working head (Column 3 Lines 65-67 and Column 4 lines 1-8) (Figure 2 and 3 item 24) a flexible tube surrounding the transport screw, connected to the working head and intended for removing the removable material or detached thrombi and emboli fragments. (Column 3 lines 19-30) (Figure 1 item 22 and 12) the transport screw forms a shearing cutting tool in cooperation with the lateral opening of the working head for comminuting materials or aspirated and/or detached thrombi and emboli penetrating between the peripheral borders of the transport screw. (Column 4 Lines 15-30)

Regarding Claim 2, Straub et al discloses *a catheter, a distal and a proximal end, a working head that is axially displaceable over a guide wire independently thereof, and is arranged at the distal end of the catheter, and has at least one lateral opening. (Column 3 Lines 65-67 and Column 4 lines 1-8), (Figure 2 and 3 item 16) a flexible transport screw that has a distal and a proximal part, extends from the proximal to the distal end of the catheter, and is capable of being rotated by means of a rotary drive of a drive unit, the rotary drive being a distance away from the working head, and the transport screw being provided with transport surfaces that extend helically along a longitudinal axis of the transport screw and in a direction of radii of the transport screw (Column 3 Lines 65-67 and Column 4 lines 1-8) (Figure 2 and 3 item 24) a flexible tube surrounding the transport screw, connected to the working head and intended for removing the removable material or the-detached thrombi and emboli fragments. (Column 3 lines 19-30) (Figure 1 item 22 and 12) the transport screw is formed in the region of the working head, as a shearing cutting tool in cooperation with the lateral*

Art Unit: 4185

opening of the working head and wherein the cutting tool, in an operating state, continuously comminutes the material or aspirated and/or detached thrombi and emboli penetrating between peripheral borders of the transport screw and borders of the lateral openings and removes them along the transport surface in a direction of the proximal end (Column 4 Lines 15-30 and line 40 to 51)

Regarding Claim 5, Straub et al discloses *the distal part of the transport screw in the region of the working head is formed so as to be an exact fit in the external diameter relative to the internal diameter of substantially cylindrical working head, so that the external diameter of the transport screw has only minimal diameter play relative to the internal diameter of an inner lateral surface of the working head. This limitation is mandatory in order to form a shearing surface between said transport screw and open slot in said working head (Column 4 Lines 23-30) (figure 6 items 32, 14a and 16)*

Regarding Claim 6, Straub et al discloses *the edges on an outside of the transport screw are formed so as to be sharp in a region of the lateral opening of the working head (Column 4 Lines 23-30)*

Regarding Claim 7, Straub et al discloses *the working head tapers towards its distal end. (Figure 2 item 16f)*

Regarding Claim 8, Straub et al discloses *the edges of the lateral opening are formed so as to be sharp at least in sections in a region of an inner lateral surface of the working head. (Column 4 Lines 23-30)*

Art Unit: 4185

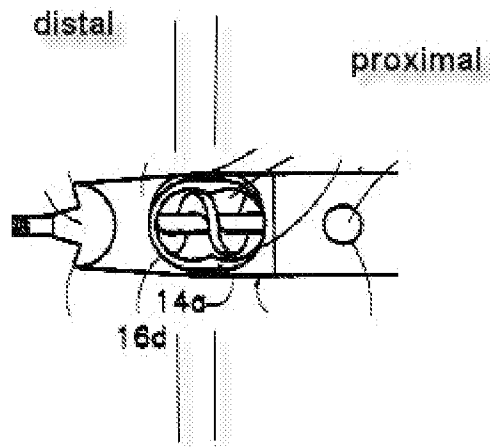
Regarding Claim 9, Straub et al discloses *edges of the lateral opening are formed so as to be rounded at least in sections in a region of the-an outer lateral surface of the working head* (Figure 2 and 3 item 16 c and d)

Regarding Claim 10, Straub et al discloses *the lateral opening is in the form of a slot* (Figure 2 and 3)

Regarding Claim 11, Straub et al discloses *the slot runs at least partially in the-an axial direction of the working head*. (Figure 3 item 14a)

Regarding Claim 12, Straub et al discloses *the slot is formed, relative to a longitudinal axis of the working head, at least partly along a helix* (Figure 3 item 16 and 32)

Regarding Claim 13, Straub et al discloses a width of the slot decreases toward a proximal end of the working head (Figure 3 item 14a and 16d)



Regarding Claim 18, Straub et al discloses the working head is connected to the tube axially in a manner resistant to tension and pressure. (Column 4 lines 57-62)

Regarding Claim 23, Straub et al *discloses the working head and/or the transport screw comprise metal, including stainless steel.* (Column 4 Lines 52-56)

Regarding Claim 24, Straub et al discloses *the working head comprises sintered ceramic: or metal ceramic or has a highly resistant layer, for protection from wear.* (Column 4 Lines 53-55)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

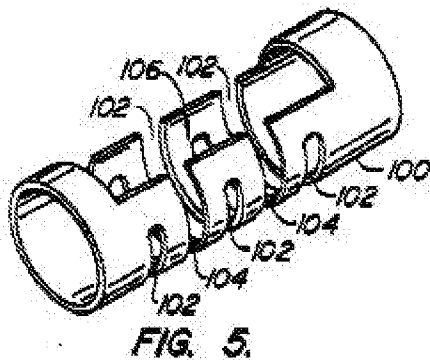
4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 3-4, 14 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al (US 5873882) as applied to claim above further in view of Evans et al (US 5312425).

Regarding Claim 3, Straub et al disclose the claimed invention except for *the lateral opening of the working head forms an L-shaped slot having a limb extending substantially in the longitudinal direction and a limb extending along a part of circumference.*

However Evans et al discloses a elongate guide frame which axially surrounds a cutting screw which form an L-shaped slot in the opening with a limb extending in the longitudinal direction an a limb extending along the circumference. (Figure 5)



item 102: Circumference limb of L-shaped slot
item 106: Longitudinal limb of L-shaped slot

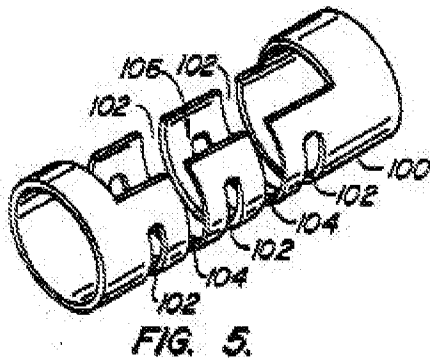
It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the L-shaped slot opening as taught by Evans et al. Doing so would create a larger cutting surface allowing the instrument to more efficiently remove undesired matter.

Regarding Claim 4, Straub et al disclose the claimed invention except for *a ratio of a width of the limb extending in the longitudinal direction to a width of the limb extending in along the part of the circumference direction is from 1.0 to 1.3*

However, the invention of Straub et al as modified by Evans et al discloses the claimed invention except for *a ratio of a width of the limb extending in the longitudinal direction to a width of the limb extending in along the part of the circumference direction is from 1.0 to 1.3*. It would have been an obvious matter of design choice to manufacture the open L-shaped slot with *a ratio of a width of the limb extending in the longitudinal direction to a width of the limb extending in along the part of the circumference direction is from 1.0 to 1.3*, since such a modification would have involved a mere change in the size of a component, the open L-shaped slot. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Regarding Claim 14, Straub et al disclose the claimed invention except for *the lateral opening of the working head forms an L-shaped slot having a limb extending substantially in the longitudinal direction and a limb extending along a part of circumference*.

However Evans et al discloses a elongate guide frame which axially surrounds a cutting screw which form an L-shaped slot in the opening with a limb extending in the longitudinal direction an a limb extending along the circumference. (Figure 5)



item 102: Circumference limb of L-shaped slot
item 106: Longitudinal limb of L-shaped slot

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the L-shaped slot opening as taught by Evans et al. Doing so would create a larger cutting surface allowing the instrument to more efficiently remove undesired matter.

Regarding Claim 25, Straub et al discloses *a catheter(12), a distal and a proximal end, a working head that is axially displaceable over a guide wire(24) independently thereof, and is arranged at the distal end of the catheter, and has at least one lateral opening.* (Column 3 Lines 65-67 and Column 4 lines 1-8), (Figure 2 and 3 item 16)

6. Claim 15-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al (US 5873882) as applied to claim 1 above, and further in view of Sjostrom (US 2003/0114875).

Regarding Claim 15, Straub et al discloses the claimed invention except for a *distal end region of the working head: at least one groove like starting from the distal end and opening in-to the lateral opening, is arranged on the-an outer lateral surface*

However, Sjostrom discloses a groove-like recess starting from the distal end of a working end and opening into the lateral opening (Figure 8 item 337)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the distal groove in the distal end traveling toward the proximal end as taught by Sjostrom. Doing so would provide greater cutting surface area and improve the cutting efficiency.

Regarding Claim 16, Straub et al discloses the claimed invention except for a *depth of the groove-like recess increases toward a proximal end of the working head.*

However, Sjostrom discloses a groove-like recess that increases in depth as it travels toward the proximal end. (Figure 8 item 337)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the distal groove which increases in depth as it travels toward the proximal end as taught by Sjostrom. Doing so would provide greater cutting surface area and improve the cutting efficiency.

Regarding Claim 17, Straub et al discloses the claimed invention except for a *width of the groove-like recess is greater than a chord of the-an internal diameter of the working head in a region of a groove base*

However, Sjostrom discloses a grooved recess which has a diameter greater than the diameter of a chord of the inner diameter of the working head. (Figure 7 item 125)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the larger diameter distal groove as taught by Sjostrom. Doing so would provide greater cutting surface area and improve the cutting efficiency.

7. Claims 19-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al in view of Cohen (US 6217565).

Regarding Claim 19, Straub et al discloses the claimed invention except for *the tube has a reinforcement in one or more sections*.

However, Cohen discloses a reinforced catheter tube (abstract line 1)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Stroub et al with the reinforced catheter as taught by Cohen. Doing so would improve the strength and longevity of the apparatus.

Regarding Claim 20 Straub et al discloses the claimed invention except for *the reinforcement is in the form of a metallic helix*.

However, Cohen et al discloses a metallic wire reinforcement braid (Column 4 lines 62-67)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the braided/helical mesh

Art Unit: 4185

reinforcement as taught by Cohen. Doing so would improve the strength and longevity of the apparatus.

Regarding Claim 21, Straub et al discloses the claimed invention except for *the reinforcement is arranged on an inside of the tube*

However, Cohen et al discloses the reinforcement on an inside of the tube.

(Figure 1 and 2 item 14)

It would have been obvious to modify the invention of Straub et al with the internally reinforced tube as taught by Cohen. Doing so would improve the strength and longevity of the apparatus.

8. Claim 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al (US 5873882) in view of Kocak (US 4705511).

Regarding Claim 22, Straub et al discloses *a tube comprising a proximal part comprising a plastic tube*. (Column 4 Lines 55-56)(Figure 1 item 22)

Straub Fails to disclose *a distal part comprising a metallic helical spring having a thin-walled elastic plastic sheath*.

However, Kocak discloses a flexible tube for intravenous use comprising a helical coiled spring (Abstract Line 3)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub et al with the helical metallic spring and sheath as taught by Kocack. Doing do would provide a flexible support structure for the tube.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Banko, Anton (US 373285), Thimsen et al (US 4844064), Stevens et al (US 4857046), Bundy et al (US 4935025), Dance et al (US 5078723).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571)2724797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/591,100

Page 14

Art Unit: 4185

/DAVID EASTWOOD/
Examiner, Art Unit 4185

/Terrell L Mckinnon/

Supervisory Patent Examiner, Art Unit 4185